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;»:		<u> </u>	Application Number		10/770,726	
TR	ANSMITTAL		Filing Date		February 4, 2004	
	<b>FORM</b>		First Named Inventor		Eugene L. BROWN et al.	
(to be used for a	all correspondence after initi	al filing)	Group Art Unit		1643	
			Examiner Name		David Harold Humphrey	
Total Number of P	Pages in This Submission 6	;	Docket Number		031896-010000 (AM101079)	
		ENCLOSU	RES (check all that apply)			
Fee Transmittal	Form		nent Papers		After Allowance Communication to Group	
Fee Attache	rd.	(for an A	Application)		pp	
	<b>, u</b>	Drawing			Appeals and Interferences  Appeal Communication to Group	
Amendment		_	tion and Power of Attorney		(Appeal Notice, Brief, Reply Brief)	
☐ ☐ Affidavits/d	leclaration(s)		ng-related Papers		Proprietary Information Status Letter	
Extension of Tir	me Request	Petition			Application Data Sheet	
Express Abando	Express Abandonment Request		to Convert to a Provisional tion	×		
Information Disclosure Statement			f Attorney, Revocation	Fo	rm PTO-1449 citing eight (8) U.S.	
☐ Certified Copy of Priority		_ `	of Correspondence Address	pa	tent, six (6) foreign patent and thirty-	
Document(s)			l Disclaimer		(36) non-patent documents and two International Search Reports.	
•	Response to Missing Parts/ Incomplete Application		Request for Refund			
l —		CD, Number of CD(s)				
Response to Mis under 37 CFR 1	_	The Commissioner is hereby authorized to charge any additional fees				
			required or credit any overpayments to Deposit Account No. 19-2380 (031896-010000) for the above identified docket number.			
	SIGNATUI	RE OF APPL	ICANT, ATTORNEY, O	R A	GENT	
Firm	Raymond Van Dyke	Reg. No.3	4,746			
<i>or</i> Individual name	Nixon Peabody LLP		<del></del>			
	409 9 <sup>th</sup> Street, N.W. Suite 900					
	Washington, D.C. 20	0004-2128				
Signature	Kan I	an a	Ql			
Date	November 2, 2005					
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In re Desent Application of:	)	
Eugene L. BROWN et al.	)	Group Art Unit: 1643
Serial No.: 10/770,726	)	Examiner: David Harold Humphrey
Filed: February 4, 2004	)	Confirmation No: 6144
For: COMPOSITIONS AND METHODS FOR DIAGNOSING, PREVENTING AND TREATING CANCERS	)	

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 Sir:

In accordance with the duty of disclosure as set forth in 37 C.F.R. § 1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98.

The documents cited in the enclosed Form-PTO-1449 are being submitted within three (3) months of the filing of this application or entry into the national stage of this application, or before the first Office Action on the merits, whichever is later, therefore no fee or certification is required under 37 C.F.R. § 1.97(b).

In view of the Official Gazette Notice dated August 5, 2003, copies of the cited U.S. patent documents are not included with this Statement. However, copies of the cited foreign patent and nonpatent literature documents, as well as the International Search Reports from related international patent applications, are enclosed.

It is requested that the accompanying PTO-1449 be considered and made of record in the aboveidentified application. It is respectfully requested that an Examiner-initialed copy of this form be returned to the undersigned.

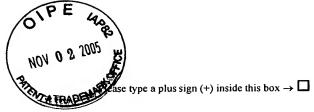
The Commissioner is hereby authorized to charge any fees connected with this filing, which may be required now, or credit any overpayment to Deposit Account No. 19-2380.

Respectfully submitted,

Date: November 2, 2005

Raymond Van Dyke Registration No. 34,746

NIXON PEABODY LLP Suite 900 401 9th Street, N.W. Washington, D.C. 20004-2128 Telephone: (202) 585-8000 Facsimile: (202) 585-8080 W669208.1



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				Examiner Nar	ne		David	d Harold Humphrey	/
Sheet	1	of 4		Attorney Doc	ket Number			96-010000 (AM10	
			U	J.S. PATENT DOC	CUMENTS				
Examiner	Cite	U.S. Patent Document							
Initials*	No.1	Number - Kind Code <sup>2</sup> (if known)		Publication Date MM-DD-YYYY		of Patentee or of Cited Docum	nent	Pages, Columns, Lines, Wh Passages or Relevant Figu	
<del></del>	†·	U.S 5,965,403	07-0	06-1999	TULLIS, F	R. H.			
	U.S 4,554,101 11- U.S 5,919,619 07-0 U.S 4,419,446 01-		01-	14-2003	FIRE, A. e	t al.			
			11-	19-1985	HOPP, T.P				
			07-0	06-1999	TULLIS, F				
			14-2003	FIRE, A. e					
			19-1985	НОРР, Т.Р	·. ·				
	T	U.S 5,141,905	10-	17-1995	MODRICH	I, P. et a	<i>l</i> .		
		U.S 5,151,254	09-2	29-1992	ARAI, H.	et al.			
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Examiner Initials	Cite No.	Foreign Patent Document  Kind Code <sup>5</sup>				of Patentee or of Cited Document  Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		Т6	
		Country Code <sup>3</sup> Number <sup>4</sup> (if know					rigares repeat	<u> </u>	
		WO 02/059376 A1		08-01-2002	SCHLEGEL, R. et al.				
		WO 03/009814 A2		02-06-2003	SCHLEGE	L, R. et	al.		
		WO 99/497354 A1	1	10-07-1999	KRUH, G.	et al.			
20.		WO 04/016810 A2		02-26-2004	SCHWIDE	TZKY,	U.		
		WO 03/104404 A2	1	12-18-2003	EBNER, R	•			
	<u> </u>	WO 02/079238 A2		10-10-2002	EULENBE	RG, K.	et al.		
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		ALLISON, J. E. et al., I	lemo	occult screening	in detecting	colorecta	al neop	olasm: sensitivity,	
		specificity, and predictive	ve va	lue. Long-term					
		Ann. Intern. Med., 112(			of S. cotonin a	nd proct	rate c	ecific membrane	+
		BURGER, M. J. et al., I antigen: their potential a 100(2):228-237, 2002	expressis dia	ession analysis of general gen	of o-catenin a s for prostrate	e cancer,	Int. J.	Cancer,	
Examiner	1				Date				

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute	for form 1449	A/PTO		Сотр	lete if Known
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/770,726		
		Filing Date	February 4, 2004		
		First Named Inventor	Eugene L. BROWN et al.		
	(	,		Art Unit	1643
		Examiner Name	David Harold Humphrey		
Sheet	2	of	4	Attorney Docket Number	031896-010000 (AM101079)

		OTHER REION ART. NON BATENT LITERATURE BOCHMENTS	
	·	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	T
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		CHEN, ZS. et al., Analysis of Methotrexate and Folate Transport by Multidrug Resistance Protein 4 (ABCC4): MRP4 Is a Component of the Methotrexate Efflux System, Cancer Res., 62:3144-3150, 2002	
		CLAROS, M. G. and VON HEIJNE, G., TopPred II: an improved software for membrane protein structure predictions, <i>Comput. Appl. Biosci.</i> , 10(6):685-686, 1994	
		COLSTON, J. T. et al., Ca <sup>2+</sup> channel alpha 1-subunit transcripts are differentially expressed in rat pheochromocytoma (PC12) cells following nerve growth factor treatment, <i>Int. J. Dev. Neurosci.</i> , 16(5):379-389, 1998	
		ENGELMAN, D. M. et al., Identifying nonpolar transbilayer helices in amino acid sequences of membrane proteins, Annu. Rev. Biophys. Biophs. Chem., 15:321-353, 1986	
		DJAMSHIDIAN, A. et al., Altered expression of voltage-dependent calcium channel alpha(1) subunits in temporal lobe epilepsy with Ammon's horn sclerosis, <i>Neuroscience</i> , 111(1):57-69, 2002	
		EPSTEIN, L. H. et al., Dopamine transporter genotype as a risk factor for obesity in African-American smokers, Obes. Res., 10(12):1232-1240, 2002	
		FEIGELSTOCK, D. et al., The human homolog of HAVcr-1 codes for a hepatitis A virus cellular receptor, J. Virol., 72(8):6621-6628, 1998	
		HONKE, K. et al., Cancer-associated Expression of Glycolipid Sulfotransferase Gene in Human Renal Cell Carcinoma Cells, Cancer Res., 58(17):3800-3805, 1998	
		ICHIMURA, T. et al., Kidney injury molecule-1 (KIM-1), a putative epithelial cell adhesion molecule containing a novel immunoglobulin domain, is up-regulated in renal cells after injury, J. Biol. Chem., 273(7):4135-4142, 1998	
		KATSURA, M. et al., Up-regulation of L-type voltage-dependent calcium channels after long term exposure to nicotine in cerebral cortical neurons, J. Biol. Chem., 277(10):7979-7988, 2002	
		KYTE, J. and DOOLITTLE, R.F., A simple method for displaying the hydropathic character of a protein, J. Mol. Biol., 157(1):105-132, 1982	
		LAI, L. and TAN, T. M., Role of glutathione in the multidrug resistance protein 4 (MRP4/ABCC4)-mediated efflux of cAMP and resistance to purine analogues, <i>Biochem.</i> J., 361(Pt. 3):497-503, 2002	
		LAUNAY, P. et al., TRPM4 is a Ca2+-activated nonselective cation channel mediating cell membrane depolarization, Cell, 109(3):397-407, 2002	
		LERMAN, C. et al., Evidence suggesting the role of specific genetic factors in cigarette smoking, Health Psychol., 18(1):14-20, 1999	

Examiner	Date	
Signature	Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date	February 4, 2004			
SIII.	(use as many sheets as necessary)		First Named Inventor	Eugene L. BROWN et al.		
	(		,	Art Unit	1643	
			Examiner Name	David Harold Humphrey		
Sheet 3 of 4		Attorney Docket Number	031896-010000 (AM101079)			

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.)., date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		LOCKHART, D. J. et al., Expression monitoring by hybridization to high-density oligonucleotide arrays, <i>Nat. Biotechnol.</i> , 14(13):1675-1680, 1996	
		MYERS, R. M. et al., Detection of sngle bse sbstitutions by rbonuclease ceavage at msmatches in RNA:DNA dplexes, Science, 230:1242-1246, 1985	
		RANALDI, G. et al., Intracellular distribution of labile Zn(II) and zinc transporter expression in kidney and MDCK cells, Am. J. Physiol. Renal Physiol., 283(6):F1365-F1375, 2002	
		SEGMAN, R. H. et al., Association between the dopamine transporter gene and posttraumatic stress disorder, Mol. Psychiatry, 7(8):903-907, 2002	
		SONG, E., RNA interference targeting Fas protects mice from fulminant hepatitis, <i>Nat. Med.</i> , 9(3):347-351, 2003	
		TENG, D. H. et al., Mutation analyses of 268 candidate genes in human tumor cell lines, Genomics, 74(3):352-364, 2001	
		UTHOFF, S. M. et al., T-cell receptor γ: a microsatellite marker for colorectal cancer, Ann. Surg. Oncol., 9(1):88-93, 2002	
		VAN AUBEL, R. A. et al., The MRP4/ABCC4 gene encodes a novel apical organic anion transporter in human kidney proximal tubules: putative efflux pump for urinary cAMP and cGMP, J. Am. Soc. Nephrol., 13 (3):595-603, 2002	
		WYATT, C. N. et al., Voltage-dependent binding and calcium channel current inhibition by an anti-alpha 1D subunit antibody in rat dorsal root ganglion neurones and guinea-pig myocytes, J. Physiol., 502 (Pt 2):307-319, 1997, Erratum in: J. Physiol. (Lond), 503(Pt 3):699, 1997	
		XU, L. L. et al., PSGR, a novel prostate-specific gene with homology to a G protein-coupled receptor, is overexpressed in prostate cancer, Cancer Res., 60(23):6568-6572, 2000	
		YAMADA, Y. et al., Genomic variation in pancreatic ion channel genes in Japanese type 2 diabetic patients, <i>Diabetes Metab. Res. Rev.</i> , 17(3):213-216, 2001	
		YUAN, T. T. et al., Cloning and genetic characterization of an evolutionarily conserved human olfactory receptor that is differentially expressed across species, Gene, 278(1-2):41-51, 2001	
		ZELCER, N. et al., Steroid and bile acid conjugates are substrates of human multidrug- resistance protein (MRP) 4 (ATP-binding cassette C4), <i>Biochem. J.</i> , 371(Pt 2):361-367, 2003	
		Affymetrix GeneChip® Expression Analysis Technical Manual	

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				Filing Date	February 4, 2004	
DIA	STATEMENT BY APPLICANT (use as many sheets as necessary)		First Named Inventor	Eugene L. BROWN et al.		
(use as many sneets as necessary)		Art Unit	1643			
				Examiner Name	David Harold Humphrey	
Sheet	4	of	4	Attorney Docket Number	031896-010000 (AM101079)	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
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		Affymetrix GeneChip® Expression Analysis, Data Analysis Fundamentals	
		PCR: A Practical Approach, McPherson, M. J. and Hames, B. D. (eds), IRL Press, at Oxford University Press, Inc., Oxford, England, 1991	
		PCR2: A Practical Approach, McPherson, M. J. and Hames, B. D. (eds), IRL Press, at Oxford University Press, Inc., Oxford, England, 1995	
		PCR Protocols: Current Methods and Applications, In: Methods in Molecular Biology, Vol. 15, White, Bruce Alan (ed.), Humana Press, Totowa, N.J. 1993	
		WWW.EBI.AC.UK/Database accession no. AAH34976 Abstract, Database EMBL [Online] EBI; 3 September 2001, HUMAN GENOME SCI INC: "Nucleic acids encloding 4277 human colon cancer-associated polypeptides, useful for preventing, diagnosing and/or treating colorectal cancers."	
		WWW.EBI.AC.UK/Database accession no. AAG75571 Abstract, Database EMBL [Online] EBI: 3 September 2001, HUMAN GENOME SCI INC: "Nucleic acids encoding 4277 human colon cancer-associated polypeptides, useful for preventing, diagnosing and/or treating colorectal cancers."	
		International Search Report for PCT/US2004/000035, mailed 08/19/04, 6 pages	
		Partial International Search Report for PCT/US2004/015645, mailed 10/25/2005, 2 pages	

Examiner	Date
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